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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 7,348,361. The application was filed on July 23, 2010, under 35 U.S.C. § 156. Please note that a patent term extension application for U.S. Patent No. 7,247,655 for NDA 22-555 for the human drug product CYSVIEW® (hexaminolevulinate hydrochloride) was filed concurrently, pursuant to the provisions of 37 C.F.R. § 1.785.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Deborah A. Somerville
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One Broadway
New York, NY 10004

RE: CYSVIEW® (hexaminolevulinate hydrochloride)
Docket No. FDA-E-2011-0133